DEC 2 2 2005

K052733

II. 510(k) Summary of Safety and Effectiveness

Company Name:

Almitech Inc.
2643 Bellmore, NY
11710 USA

Contact Name:

Alex Breytman
President
Phone: (516) 343-3050
Fax: (516) 221-0878

Date Prepared: (9)/(25)/2005

2.1 Device Name:

Proprietary name: Almitech Inc. Dental Implant System
Common/Usual Name: Endosseous Dental Implant
Trade Name: Almitech Inc. Dental Implant System

The device has been classified in Class II under the following classification:

Classification name	*Product Code*	*Regulation Number*	*Panel Identification*
Endosseous Implant	DZE	872.3640	Dental Devices Panel

2.2 Description of the Device:

Almitech is an Endosteal Root-form (Cylindrical) Implant. The implant system consists of multiple components that are precision-machined and are manufactured from grade-4 pure titanium or a medical grade titanium alloy.

Implants: Almitech implant (See attachment 5, 6, 7) is intended for either single-stage or two-stage surgical placement. Implant consist of fine pitch threads with 60° profiles, spherical tips and have two cutting grooves that give the implant its self-tapping feature. The outside surface is sandblasted with calcium phosphate abrasive to create surface roughness about Ra= 70μIN. (See Blasted surface information Attachment 1, 2, 3, 4). The inside of the implant consists of 8° Morse taper with three cutouts to drive it in place and provide positioning to abutment and threaded hole to deliver abutment in to place.

Cover screw / healing caps: The cover screws and healing caps (See attachment 8, 9) are manufactured from grade 4 titanium and are placed in the implant using a Hex Tool. Using the 1.25mmD Hex Tool, by carrying the cover screw/healing cap to the surgical site thread it into the implant. Suture the soft tissue over the implant or around the cover screw (healing cap) or transmucosal neck. The cover screw/ healing cap keeps free from in-growth of bone and soft tissue as well accumulating debris by occluding the internal surface of the implant. The parts are found freely floating inside a sterile individual Tyvek pouches.

Abutment systems and superstructures: The abutment (See attachment 10, 11) selection process occurs at the start of the prosthetic procedure and is dependent on the measurement of gingival thickness. After adequate osseo-integration the implants should be uncovered if necessary and the cover screw should be removed. The internal part of the implant irrigated, freed from debris and dried. The appropriate abutment should be placed, by using an inserting driver (1.25mmD Hex Tool) and a torque wrench applying 30 Ncm of torque. Once the abutment is fit on the implant, it delivers maximum stability with the use of the torque wrench.
Solid Abutments do not have to be modified but can be, and if it is necessary to modify the abutments, carbide or a diamond bur can be used with copious irrigation.
Abutments are not to be over-prepared, taking into consideration retention of restoration and strength of the abutment. It is not recommended to modify the abutment at the junction with implant.

Surgical Instruments: The range of instruments made available as part of the Almitech Inc. Dental Implant System include: drills, adapters, implant inserts, screw drivers, torque ranges, ratchets and metal cassettes for sterilization.

2.3 Indications for Use:

The implant system is intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, freestanding bridges and to retain over dentures by means of o-ring abutments or bar-attachments

2.4 Predicate Devices:

The data submitted in this 510(K) is aimed toward demonstrating substantial equivalence of Almitech Inc. Dental Implant System to ITI Solid screw implant (K894593), (K894595), (K971578), (K920768), Blue Sky Bio Dental Implant System (K010882), and Paragon Screw-Vent System (K950578), (K861426). Almitech Inc. Dental Implant System is compatible to the three Dental Implant Systems examined above and all contain implants, cover screws and healing cups, abutments, and the applicable surgical instruments. All other technological characteristics are similar, and all four devices show equivalent performance characteristics.

2.5 Substantial Equivalence Chart:

Feature	Almitech Inc. Dental Implant System	ITI Solid screw implant K894593, K894595, K971578, and K920768	Blue Sky Bio Dental Implant System K010882	Paragon Screw-Vent System K950578, K861426
Material	CP Titanium Grade 4	CP Titanium Grade 4	CP Titanium Grade 4	CP Titanium Grade 4
One Stage	Yes	Yes	Yes	No
Coating	Blasted with resorbable medium, HA	TPS	Blasted with resorbable medium	Blasted with resorbable medium, HA
Body Diameter (mm)	3.3, 4.1, 4.8,	3.3, 4.1, 4.8	3.3, 4.1, 4.8	3.7, 4.7, 6.0
Collar Diameter (mm)	3,3;4,1;4.8; 5.6	3.5;4.1;4.8, 6.5	4.1;4.8, 6.5	3.7, 4.7, 6.0
Collar Height (mm)	1.8	1.8, 2.8	1.8, 2.8	1.0
Lengths (mm)	8, 10, 12, 14, 16	8, 10, 12, 14, 16	8, 10, 12, 14	8, 10, 13, 16
External Screw Threads	Yes	Yes	Yes	Yes
Anti-rotational feature	Internal Taper 8°	Internal Taper 8°	Internal Taper 8°	Internal Hex
Gamma Sterilized	Yes	Yes	Yes	Yes
Solid Abutment for Cemented Restoration	Yes	Yes	Yes	Yes
O-ring Abutment for partial or full overdenture	Yes	Yes	Yes	Yes
Instruments (surgical and restorative)	Yes	Yes	Yes	Yes
Intended Use	Implantation into the fully or partially edentulous ridge for support of single of multiple unit prosthesis.	Implantation into the fully or partially edentulous ridge for support of single of multiple unit prosthesis.	Implantation into the fully or partially edentulous ridge for support of single of multiple unit prosthesis.	Implantation into the fully or partially edentulous ridge for support of single of multiple unit prosthesis.

2.6 Conclusion:

The evaluation of Almitech Inc. Dental Implant System does not raise any new questions of safety or effectiveness and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Mr. Alex Breytman
President
Almitech, Incorporated
2643 Bedell Street
Bellmore, New York 11710

Re: K052733
Trade/Device Name: Almitech Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: November 29, 2005
Received: November 30, 2005

Dear Mr. Breytman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) Number:

Device Name: Almitech Dental Implant System

INDICATIONS FOR USE:

The implant system is intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, freestanding bridges and to retain over dentures by means of o-ring abutments or bar-attachments

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K052733

Prescription Use X OR Over- The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052733